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JUN 20 2008

Traditional 510(k): Device Modification – Horizon XVu

Terminology

Horizon XVu = Subject of this 510(k). The Horizon XVu is a modified device, a system identical to the Horizon SE Cathlab but with different graphic user interface.

Horizon SE = The predicate device. The Horizon SE Cathlab was cleared for marketing by the FDA (K032997)

Intended Use of the Horizon SE/Horizon XVu:

The Horizon XVu is a state-of-the-art computerized laboratory, capable of acquiring and displaying essential patient data such as ECG/Heart Rate, invasive blood pressures, pulse oximetry, respiration, cardiac output, body temperatures and EtCO2.
Heart rate, multi-lead ECG and BP waveforms from different heart sites are continuously presented on the Physiological Waveform Display. The hemodynamic data, waveform and numerical, can be stored, recorded, analyzed and presented in a variety of report formats.

Device Description: Horizon XVu

The prime function of the Horizon XVu (Cathlab) is to acquire and display vital-sign data and waveforms in real time during the catheterization process, creating a fully documented case history.

Functional Description of the Horizon XVu

The Horizon XVu is capable of acquiring and displaying essential patient data such as ECG/Heart Rate, invasive blood pressures, pulse oximetry, respiration, cardiac output, and body temperature. Heart rate, multi-lead ECG, EtCO2 and BP waveforms from different heart and vascular sites are continuously presented on the Physiological Waveform Display.
The hemodynamic data, waveform and numerical, can be stored, recorded, analyzed and presented in a variety of report formats.

The Horizon XVu is used for activities such as coronary and peripheral endovascular procedures and Angioplasty. The basic steps described above (catheter positioning, site definition/acquisition, analysis and acceptance) are performed as an integral part of these procedures.

The system has a Sun Ultra 25 computer that utilizes powerful, real-time, software to control the system operation and to process the vital patient sign data measurements acquired from the CFE or entered manually at the keyboard.

A Laser Printer is provided in the system. This provides printouts of textual and graphical summaries of all patient data and catheterization procedures.

Base Configuration: Cathlab parameters

- 4 Invasive Blood Pressure channels
- Diagnostic 7 or 12 Lead ECG
- Non-invasive Blood Pressure
- Pulse Oximetry (SpO_2)
- EtCO2 (optional)

Horizon XVu Options:

- Full Disclosure
- Off-line workstations
- Remote Interactive terminal
- Angiography Analysis Package
- CDR, DVD or Optomagnetic drive
- Choice of Console Table – regular, enhanced, compact or without consol

Main components of the Horizon XVu:
The Horizon XVu system consists of:

(A) a **Front End unit** and
(B) a **Central system**

(A) The "**Cathlab Patient Front End**" (CFE) acquires, processes, and converts vital signs from the patient into digital signals. The CFE then sends the digitized signals and data, via a network connection, to the central system of the Horizon XVu for process and display.

The CFE can acquire the following physiological signals of the patient:

- ECG – the CFE acquires an ECG waveform and measures Heart Rate

- Blood Pressure – the CFE acquires a BP waveform and measures Systole, Diastole and Mean Pressure
- Temperature – the CFE measures Temperature by means of a numeric value in C° or F°
- SpO_2 – the CFE acquires and measures oxygen saturation and creates a photoplethysmographic waveform and numeric value of the oxygen saturation
- EtCO2 – the CFE measures CO2 during the respiration cycle and present the end tidal (end expiratory) CO2 and the inspired CO2 - inCO2 and the respiration rate - RR

(B) The **Central System** contains the following main devices:

- A SUN® OEM Workstation (computer) – see details on the Sun workstation below
- Two local LCD displays
- Video line driver
- AC Power Unit
- Laser printer
- Hub
- Modem
- Opto-magnetic disk (optional)

Reasons for replacing the graphic user interface of the Horizon SE:
The Horizon SE used a GUI – Graphic User Interface with a stile that was useful at the time of the original release of the Horizon SE (Horizon 9000) release.

During the years, with the movement of computers toward Windows platform there was a need and client request to change the GUI to a more modern look.

This new GUI is more users friendly and will give the system a more modern look without changing the signal acquisition, storage and report capabilities.

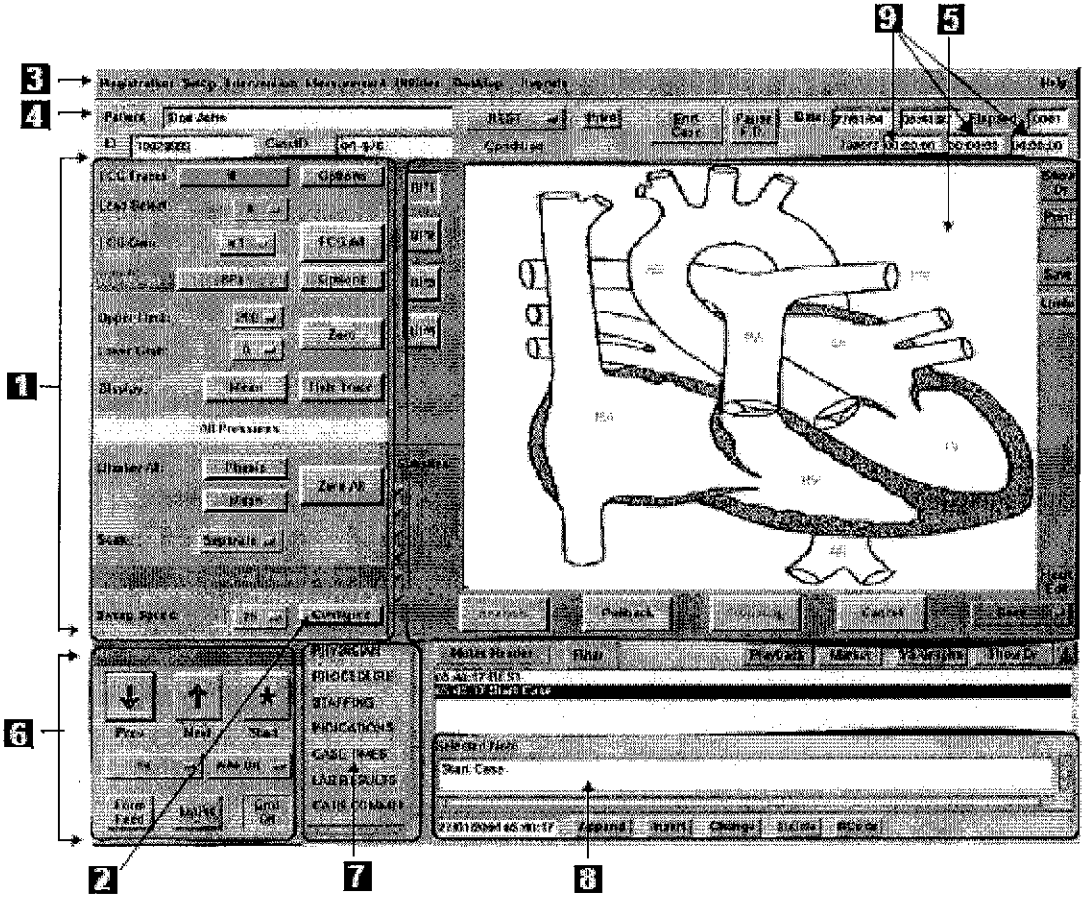
The advantages of the **Horizon XVu** on the **Horizon SE Cathlab** are:
User friendly
Modern look

Description of the design of the Horizon XVu

The Horizon XVu uses the same CFE front end electronics and the same hardware platform as the Horizon SE.
The list of functions and protocols was not changed.

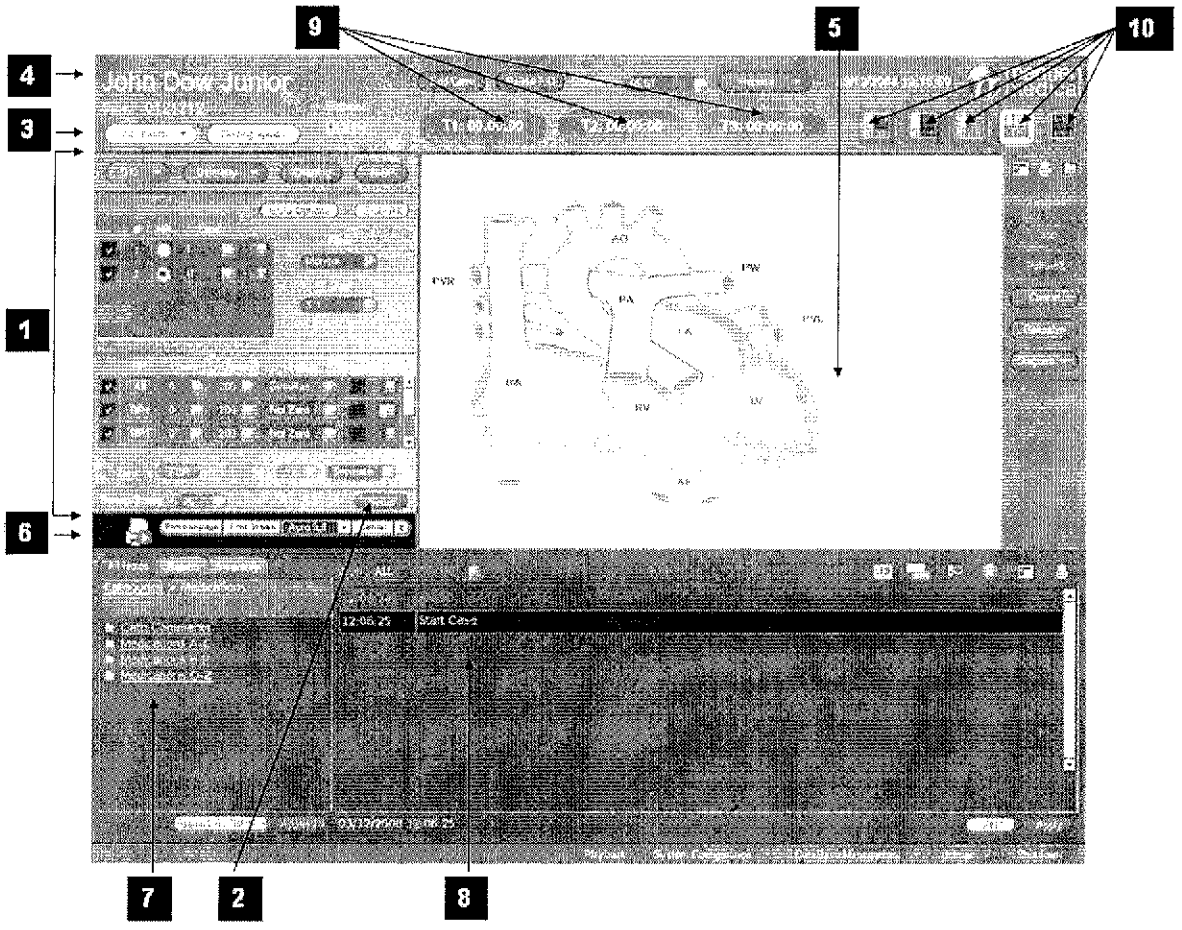
The control panels and information lists where not modified, but the GUI view and colors, were modified to use new colors with better contrast and easier user interface.

Horizon SE Technician screen



Horizon XVu Technician Screen

K081484



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 2008

Mennen Medical Ltd.
c/o Mr. Ifat Oren
QA and Regulatory Affairs
4 Ha-Yarden Street, PO Box 102 Rehovot
Yavne 76100
ISRAEL

Re: K081484
Trade Name: Horizon XVU
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK
Dated: May 21, 2008
Received: May 28, 2008

Dear Mr. Oren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

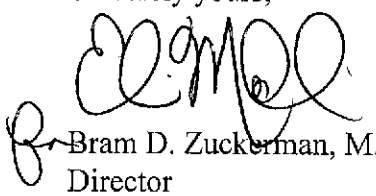
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **Horizon XVU**

Indications For Use:

The Horizon XVu is a state-of-the-art computerized laboratory, capable of acquiring and displaying essential patient data such as ECG/Heart Rate, invasive blood pressures, pulse oximetry, respiration, cardiac output, body temperatures and EtCO2.

Heart rate, multi-lead ECG and BP waveforms from different heart sites are continuously presented on the Physiological Waveform Display. The hemodynamic data, waveform and numerical, can be stored, recorded, analyzed and presented in a variety of report formats.

*The Intended Use of the Horizon XVU is same as the Indications For Use as indicated above.

Prescription Use YES AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081484